

## REMARKS

### Summary of the Invention

The invention features a biologically pure culture of a newly identified single-celled organism, designated Spiky Rotating Cells (SPR). The invention also features methods for diagnosing an SPR infection, an instrument for collecting a secretion containing SPR and for detecting an SPR infection in the secretion, and methods for treating an SPR infection.

### Support for the Amendments

Support for the amendments to claims 1, 2, 5, 6, 9, 10, 12, 14, and 16 is found on page 6, lines 11-14, page 7, lines 6-21, page 8, lines 8-10, and page 9, line 3, through page 10, line 15. Support for new claims 18-34 can be found in figure 4, and on page 6, line 18, page 7, lines 6-7 and line 21, page 9, lines 3, through page 10, line 15, and page 12, line 9-12.

### Summary of the Office Action

Claims 1-17 are pending. Claims 1-2, 4, 5-13, and 17 are rejected under 35 U.S.C. § 112, second paragraph. Claims 1-8, and 10-17 are rejected under 35 U.S.C. § 102(b). Claims 5, 10, 11, and 14-16 are rejected under 35 U.S.C. § 102(e). Claims 7-8 are rejected under 35 U.S.C. § 103(a) for obviousness over *Caillouette et al.* (U.S. Patent No. 5,928,165) in view of *Kalb et al.* (U.S. Patent No. 5,704,353). Claim 9 is rejected under 35 U.S.C. § 103(a) for obviousness over *Caillouette et al.* (U.S. Patent No. 5,928,165) in view of *Kalb et al.* (U.S. Patent No. 5,704,353) and further in view of *Sheiness et al.* (U.S. Patent No. 5,776, 694).

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-2 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 1-2 have been amended to more clearly describe the claimed organism by reciting additional defining characteristics. Claim 1 now clearly defines the organism, Spiky Rotating Cells (SPR), as a protozoan with the following seven features: (i) a spherical shape measuring approximately 7-8  $\mu\text{m}$ ; (ii) a protozoan having spiky membrane projections; (iii) a protozoan having a refractile cell membrane; (iv) a protozoan exhibiting rotatory motility; (v) a protozoan, said protozoan forming periodic colonies of 2 to 1000 cells; (vi) a protozoan, said protozoan living in an extracellular environment; and (vii) causes disease in humans. Support for this amendment is found throughout the specification, *e.g.*, on page 7, lines 12-21.

Claim 2 has been amended to recite the ATCC Deposit No. for the organism SPR.

Claim 4 was rejected for failing to clearly define the recited diameter measurement of the claimed organism. Claim 4 has been cancelled and claim 1 has been amended to recite a protozoan with “a spherical shape measuring approximately 7-8  $\mu\text{m}$ ,” which indicates that the diameter measurement refers to the single-celled stage of the protozoan SPR.

Claims 5-13 were rejected for failing to correlate the method of diagnosis of an SPR infection with the actual diagnosis. Claims 5-13 have been amended and new claims 22-34 have been added to more clearly recite the method of diagnosis and to establish a correlation of the results with a diagnosis. Specifically, claims 5, 22, and 24 correlate the presence of SPR in a sample with either an SPR infection or nongonococcal urethritis, or a propensity for developing nongonococcal urethritis. Claim 23 correlates both the presence of SPR and a pH greater than 6.0 in a sample with nongonococcal urethritis or a propensity for developing

nongonococcal urethritis.

Claim 5 was rejected for omitting essential steps in the method of diagnosis of an SPR infection. Claim 5 has been amended as discussed above.

Claims 5-8, and 10-13 were rejected for omitting essential elements; specifically, the material that would provide the means for testing and result in a diagnosis. Claims 5, 6, 10, and 12 have been amended, and new claims 22-34 have been added to clarify these elements.

Claims 6, 10, and 12 were rejected for failing to provide antecedent basis for the word "secretion." Claims 6, 10, and 12 have been amended to specify that the sample is the collected secretion.

Claim 17 was rejected for not distinctly reciting the SPR infection to be treated. The rejection of claim 17 may now be withdrawn in light of the amendment to claim 1, from which claim 17 depends.

In light of the foregoing amendments and remarks, Applicant respectfully requests that the rejection of claims 1-2, 4-13, and 17, for indefiniteness be withdrawn.

#### Rejections Under 35 U.S.C. § 102(b)

##### *Rejection of claims directed to a biologically pure culture of a single cell organism*

Claims 1, 2, 3, and 4 were rejected for lack of novelty over *Ruffer et al.* (claim 1; hereinafter "*Ruffer*"), *Relman et al.* (U.S. Patent No. 6,214,548; claims 1-4; hereinafter "*Relman*"), *Monteiro-Leal et al.* (Claims 1-4; hereinafter "*Monteiro-Leal*"), *Hartskeerl et al.* (claims 1-2; hereinafter "*Hartskeerl*"), and *Abou El Seoud et al.* (claims 1-4; hereinafter "*Abou El Seoud*"). Several of the cited references identify a one-celled organism that is spiky and

rotates. None of these references, however, describe the organism defined in claim 1 as amended.

Claim 1 now requires a biologically pure culture of a single-celled organism in which the organism is a pathogenic protozoan having the following characteristics: a spherical shape measuring approximately 7-8  $\mu\text{m}$ , spiky membrane projections, a refractile cell membrane, rotatory motility, periodic colony formation consisting of 2 to 10,000 cells, and that lives in an extracellular environment. Not one of the cited references (*Ruffer*, *Relman*, *Monteiro-Leal*, *Hartskeerl*, or *Abou El Seoud*) recites all of the limitations found in amended claim 1.

*Ruffer* describes a *Chlamydomonas* cell as having “two flagella...in combination with the rotation of the cell.” (Page 111, first paragraph). *Ruffer* does not describe a protozoan with a spherical shape measuring approximately 7-8  $\mu\text{m}$  in diameter, which exhibits spiky membrane projections, a refractile cell membrane, rotatory motility, and periodic colony formation consisting of 2 to 10,000 cells.

*Relman* describes a *Cyclospora* cell, which “is an emerging human intestinal pathogen...[with] oocyst-like structure...detected in the stool of humans with diarrhea. These structures are spherical...[and] 8-10  $\mu\text{m}$  in diameter.” (Column 2, lines 42-46) *Relman* does not describe a protozoan exhibiting spiky membrane projections, a refractile cell membrane, rotatory motility, and periodic colony formation consisting of 2 to 10,000 cells.

*Monteiro-Leal* describes:

*Tritrichomonas foetus*...[which] is a protozoon parasite of the urogenital tract of cattle. Sexually transmitted, the cell exerts its pathogenicity (epithelial lesions, infertility, and abortion) interacting with the epithelial cells of the host...Previous studies...have shown that the anterior flagella of *T. foetus* show a ciliar-type beating... (page 206, first paragraph)

The cell also performs rotational movements. (abstract)

*Monteiro-Leal* does not describe a spherical protozoan measuring approximately 7-8  $\mu\text{m}$  in diameter, which lives in an extracellular environment, exhibits spiky membrane projections and a refractile cell membrane, and forms periodic colonies of 2 to 10,000 cells.

*Hartskeerl* describes *Septata intestinalis*, which exhibits “type I tubular appendages.”

*Hartskeerl* does not describe a pathogenic, spherical protozoan measuring approximately 7-8  $\mu\text{m}$  in diameter, which exhibits spiky membrane projections, a refractile cell membrane, rotatory motility, and periodic colony formation consisting of 2 to 10,000 cells.

*Abou El Seoud* describes “*Trichomonas vaginalis* [which] is a flagellated protozoon of the urogenital tract in humans...It commonly causes vaginitis and sometimes cervicitis in women and urethritis in both sexes...” (See page 263, lines 1-4) *Abou El Seoud* does not describe a spherical protozoan measuring approximately 7-8  $\mu\text{m}$  in diameter, which exhibits spiky membrane projections, a refractile cell membrane and periodic colony formation consisting of 2 to 10,000 cells.

Claim 1, as amended, now recites several limitations, none of which are all found in any of *Ruffer*, *Relman*, *Monteiro-Leal*, *Hartskeerl*, or *Abou El Seoud*. More specifically, none of the cited references describe a single-celled organism that exhibits a refractile cell membrane and furthermore, none of the references describe a single-celled organism that exhibits periodic colony formation, a unique characteristic exhibited by the organism of the instant invention. In light of these clarifying remarks and amendments, Applicant respectfully requests withdrawal of the rejection of claims 1-4.

*Rejection of Claim 5: A Method of Diagnosing SPR Infection in a Human Patient*

Claim 5, drawn to a method of diagnosing an SPR infection in a human patient, was rejected for lack of novelty over *Relman, Abou El Seoud, Andrews et al.* (U.S. Patent No. 5,300,491; hereinafter “*Andrews*”), *Caillouette et al.* (U.S.P.N. 5,827,200, hereinafter “*Caillouette ‘200’*”), *Caillouette et al.* (U.S.P.N. 5,928,165, hereinafter “*Caillouette ‘165’*”), *Mennen et al.* (U.S. Patent No. 4,108,729; hereinafter “*Mennen*”), and *Yeh et al.* (U.S. Patent No. 5,725,373; hereinafter “*Yeh*”). Applicant respectfully disagrees.

None of the cited references specify obtaining a sample from a patient, followed by testing the sample for the presence of SPR. *Relman* describes the collection of “fecal specimens...from patients with watery diarrhea or diarrheal disease, and screening microscopically for cyclosporin oocysts.” (Column 17, lines 25-64; Emphasis Added) *Relman* does not disclose testing for the presence of SPR, furthermore, the method of the instant invention involves detecting SPR in vaginal or urethral secretions, not fecal samples.

The Examiner has rejected claim 5 (and dependent claims 6, 10, and 12) over *Abou El Seoud*, which describes “routine diagnosis...[of Trichomonas vaginalis by] microscopic identification of the parasite.” (Page 263, lines 11-12) *Abou El Seoud* discloses diagnosis of *T. vaginalis*, not SPR, as is required by the instant invention. Therefore, *Ebou el Seoud* does not describe all of the limitations of claim 5 and claims dependent therefrom.

*Andrews* describes a method for treating human pathogens with a divalent metal salt of bacitracin. *Andrews* discloses obtaining pathogenic samples, but there is no mention of testing those samples for the presence of any pathogen (e.g., see column 8, line 65, through column 9, line 3, of U.S.P.N. 5,300,491). Therefore, *Andrews* does not require all of the claim limitations

of instant claim 5.

The Examiner has rejected claim 5 (and dependent claims 10 and 11) over *Caillouette* '200 and *Caillouette* '165, which both describe a device that can be used “in the method of detecting pathogenic bacteria in the vagina.” (Abstract of '200 and '165) Neither reference discloses a method of obtaining a sample and testing the sample for the presence of SPR. *Caillouette* '200 and *Caillouette* '165 disclose the function and/or characteristics of the device, not a method to use the device to obtain and test a sample for the presence of an SPR infection. Therefore, neither *Caillouette* '200 nor *Caillouette* '165 recite all of the limitations of claim 5, and claims 10 and 11 which depend therefrom.

Finally, the Examiner rejects claim 5 (and claims 6, 7, and 8 which depend from claim 5) over *Mennen*, which discloses the use of a paper booklet for diagnosing *Neisseria Gonorrhoeae*. *Mennen* does not disclose a method of diagnosing an SPR infection. Furthermore, the detection device described in *Mennen* requires that the specimen be “collected on the strip” of the paper booklet, a drop of saline must then be added to the target circle and the booklet must then be squeezed “to permit the specimen collected on [the] strip...to interact with [a chromogenic] reagent in [the] strip...[to] create color which presumptively diagnoses *Neisseria Gonorrhoeae* in the male.” (Column 2, lines 22-33) This method differs significantly from the method of instant claim 6, which requires obtaining the sample directly from the urethra of a male patient, and instant claim 7, which requires a pH indicator. *Mennen* is also silent on the presence of an instrument that “includes a loop sized and shaped for insertion into the distal end of the urethra for secretion collection,” which is required by instant claim 8. As stated above, *Mennen* discloses a paper booklet that is clearly not meant to be used in the same manner as the

collection means of the instant invention.

The Examiner rejects claim 5 (and dependent claims 12 and 13) over *Yeh*, which discloses a periodontal probe used for “diagnosing periodontitis and tooth decay” using “acid detecting litmus in the test paper band unit which releasably [attaches] to the probe tip free end side.” (Column 1, line 8, and lines 57-60) *Yeh* fails to disclose a method of obtaining a sample and testing the sample for the presence of SPR.

Applicant asserts that the prior art is silent with respect to a single-celled organism, termed SPR, with the characteristics defined in instant claim 1. Therefore, the method presented in any of *Relman*, *Abou El Seoud*, *Andrews*, *Caillouette* ‘200, *Caillouette* ‘165, *Mennen*, or *Yeh* fails to disclose a means for diagnosing an SPR infection, as is required by instant claim 5. In light of this statement and the above arguments, Applicant kindly requests withdrawal of the rejection of claim 5 and dependent claims 6-8, and 10-13.

*Rejection of Claims 14 and 16: An Instrument for the Collection of a Sample*

The Examiner has rejected claims 14-16 for lack of novelty over *Mennen*, *Caillouette* ‘165, and *Caillouette et al.* (U.S.P.N. 5,577,512 and U.S.P.N. 5,425,377, hereinafter “*Cailloutte* ‘512 and ‘377”) because they disclose and claim an instrument for the collection of a sample, wherein the instrument also comprises a pH sensor. Applicant respectfully disagrees.

The Examiner states that claims 14 and 15 lack novelty over *Mennen*. *Mennen* provides “a paper booklet for the presumptive diagnosis of *Neisseria Gonorrhoeae*” in which a specimen is added to the booklet and forced by squeezing or tapping “to permit the specimen collected on [the] strip...to interact with [the chromagenic] reagent in [the] strip...and create color which



presumptively diagnoses *Neisseria Gonorrhoeae* in the male.” (Column 2, lines 22-33) The paper booklet disclosed by *Mennen* does not comprise a “handle portion” attached to which is “a means for collecting secretions from the reproductive system of a male patient, wherein said collecting means comprises a loop...[and] a pH sensor positioned adjacent to the collecting means, wherein said pH sensor comes into contact with [the] sample,” as is required by amended instant claim 14. *Mennen* discloses the use of a chromogenic reagent for the detection of the pathogen. The instrument of instant claim 14, however, requires a pH sensor. Therefore, Applicant asserts that the instrument disclosed by *Mennen* does not require all of the limitations of the instrument of the instant invention.

The Examiner states that claims 14-15, and 16 are anticipated by *Caillouette* ‘165 and that claim 16 is anticipated by *Caillouette* ‘512 and ‘377. The ‘165, ‘512, and ‘377 patents disclose a “carrier stick” that provides “a pH indication means...at one end portion...of the stick...and a swabbing means...on the opposite end portion...of the stick.” (see *e.g.*, column 4, lines 20-30 of ‘165) The center of the stick is used for handling. Neither *Caillouette* ‘165, or *Caillouette* ‘512 and ‘377 disclose a collection means that consists of a loop region, as is required by instant claim 14. The presence of the loop region in the instant invention clearly distinguishes the instant invention from the instruments of the above-cited references. Therefore, withdrawal of the rejection of claims 14-16 is respectfully requested.

*Rejection of Claim 17: A Method of Treating an Infection in a Patient*

The Examiner rejects claim 17 for lacking novelty over *Birthisle et al.* (hereinafter “*Birthisle*”), *Gray et al.* (U.S. Patent No. 5,474,997; hereinafter “*Gray*”), and *Larson et al.*

(U.S. Patent No. 6,180,136 B1; hereinafter "*Larson*"). Applicant respectfully traverses this rejection.

*Birthisle* teaches the administration of metronidazole to a patient for the treatment of a microsporidial infection. *Gray* teaches the administration of itraconazole for treatment of fungal, yeast, and dermatophyte infections. *Larson* teaches the administration of ofloxacin for the treatment of infection caused by a protozoan. None of these references specifically teach the administration of metronidazole, itraconazole, or ofloxacin for the treatment of an SPR infection. The protozoan SPR organism has been characterized by seven features (discussed above) that distinctly separate SPR from microsporidia, yeast, bacteria, and all other known protozoa. The use of these agents to treat an SPR infection is not disclosed in any of the references cited above. Based on the above argument, withdrawal of the rejection of claim 17 is respectfully requested.

#### Rejections under 35 U.S.C. § 103

Claims 7-8 are rejected under 35 U.S.C. § 103 over *Caillouette* '165 in view of *Kalb et al.* (U.S. Patent No. 5,704,353; hereinafter "*Kalb*"). The Examiner states that *Caillouette* '165 "discloses a method of diagnosing infection that utilizes a collection instrument that contains a pH indicator...and...has the shape of a loop," but that "fail[s] to teach the instrument...formulated for a male urethra." *Kalb* provides a collection instrument for obtaining a male urethral secretion. The Examiner then states that "it would have been obvious to the person of ordinary skill in the art to obtain a male urethra sample with an instrument as taught by *Caillouette* '165 formulated for a male, as suggested by *Kalb et al.*" As discussed above,

however, the instrument of *Caillouette* '165 would fail to properly collect the sample for examination because it possesses a cotton swab as the collecting means. The instrument of the instant invention features a loop region "sized and shaped for insertion into the distal end of the urethra for secretion collection." (Claim 8) This design, which "is a streaking loop commonly used to plate microorganisms" (page 9, lines 11-12, of the specification), specifically aids in the acquisition and detection of the SPR organism. The use of cotton swabs is incompatible with the method of the instant invention because the SPR organism cannot be sufficiently separated from a collection means consisting of a cotton swab due to the absorbent properties of the cotton. Therefore, even if one skilled in the art would be motivated to provide the instrument of *Caillouette* '165 for collection of a male urethral sample using the formulation of *Kalb*, the instrument would fail to provide the same function as the instrument of the instant invention, which is to provide a collection means that will allow satisfactory collection and examination of the SPR organism. Applicant submits that claims 7-8 are in condition for allowance and withdrawal of the rejection of claims 7-8 is respectfully requested.

Claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Caillouette* '165 in view of *Kalb* and *Sheiness et al.* (U.S. Patent No. 5,776,694; hereinafter "*Sheiness*"). The Examiner states that *Caillouette* '165 discloses "a method of diagnosing infection...[using a] sample collected from a human patient urethra," while *Kalb* discloses "obtaining a sample for urethra secretion pH analysis." The Examiner continues by stating that the *Caillouette* '165 and *Kalb* references, when combined with *Sheiness*, which "provides and teaches the classical method for diagnosis of an infectious organism through observing the pathogen...in a wet mount," would have made it obvious "to the person of ordinary skill in the art at the time...to

diagnose 'SPR' infection using a method of...obtaining a urethral sample...and testing the sample based upon pH and microscopic inspection." Applicant respectfully disagrees.

As discussed above in regards to the rejection of claims 7 and 8, both *Caillouette* '165 and *Kalb* fail to teach or suggest an instrument comprising a loop sized and shaped for insertion into the distal end of the urethra for collecting urethral secretions, as is required by instant claim 8, from which claim 9 depends. *Sheiness*, which only discusses the use of microscopy for the identification of *Trichomonas*, also fails to supply this missing element. Thus, the combination of *Caillouette* '165, *Kalb*, and *Sheiness* fail to teach or suggest all of the claim limitations recited in claim 9. Therefore, Applicant respectfully requests that the rejection of claim 9 may now be withdrawn.

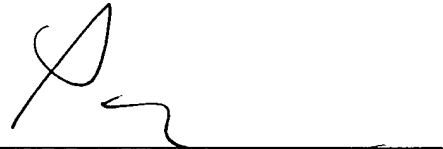
#### CONCLUSION

Applicant submits that the claims are now in condition for allowance, and such action is respectfully requested. Enclosed is a petition to extend the period for replying for three months, to and including January 18, 2002. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date:

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PATENT TRADEMARK OFFICE

Version with markings to show changes made

In the Specification:

A marked-up version of the paragraph on page 12, lines 9-12, of the specification is presented below.

A biologically pure culture, as defined herein, of SPR was deposited with the American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209 on June 18, 2000, and given ATCC accession number PTA-2129.

A marked-up version of the paragraph on page 7, lines 12-21, of the specification is presented below.

Accordingly, the invention features a biologically pure culture of the single-celled organism Spiky Rotating Cells (SPR). Preferably, the culture has the biological characteristics of the SPR sample, ATCC Deposit No. PTA-2129, received at the ATCC on June 18, 2000. The SPR organisms of the culture preferably exhibits the following biological characteristics (a) spherical shape, (b) motile in an imperfect rotating manner, (c) multiple spiky membrane projections, (d) highly refractile cell membrane when viewed, e.g., by Darkfield microscopy. Preferably, further characteristics are: (e) approximately 7-8  $\mu\text{m}$  in diameter, (f) provisionally classified as a protozoan, (g) periodic colonial morphology, and (h) preferential proliferation in Diamond's Media.

A marked-up version of the paragraph on page 11, lines 21-23 through page 12, line 1, of the specification is presented below.

I have found that several commercially available drugs are effective in treating infection with SPR. One such drug is itraconazole, sold under the trade name SPORANOX [Sporanox] ®, available from Jansen Pharmaceuticals. The patient ingests one 200 mg tablet per day for three-four weeks.

A marked-up version of the paragraph on page 12, lines 2-4 of the specification is presented below.

Another drug that can be used to treat SPR infection is metronidazole, sold under the trade name FLAGYL [Flagyl] ®. The patient takes 500 mg twice per day for six weeks.

A marked-up version of the paragraph on page 12, lines 5-7 of the specification is presented below.

Yet another drug that is effective in treating SPR infection is ofloxacin, sold under the trade name FLOXIN [Floxin] ®. The patient takes 400 mg twice per day for two weeks.

In the Claims:

Marked-up versions of claims 1, 5-6, 9-10, 12, 14, 16, and 17 are presented below.

1. (Amended) A biologically pure culture of a [the] single-celled organism, Spiky Rotating Cells (SPR), wherein said organism is a protozoan and comprises the following characteristics: (i) a spherical shape measuring approximately 7-8  $\mu$ m; (ii) a protozoan having spiky membrane projections; (iii) a protozoan having a refractile cell membrane; (iv) a protozoan exhibiting rotatory motility; (v) a protozoan, said protozoan forming periodic colonies of 2 to 10,000 cells; (vi) a protozoan, said protozoan living in an extracellular environment; and (vii) causes disease in humans.

2. (Amended) The biologically pure culture [of Spiky Rotating Cells] of claim 1, wherein said organism has [having] the biological characteristics of [the single-celled Spiky Rotating Cells of] ATCC [A.T.C.C.] Deposit No. PTA-2129.

5. (Amended) A method of diagnosing an SPR infection in a human patient, said method comprising the steps of:  
a) obtaining a sample from said patient; and  
b) testing said sample for the presence of SPR, wherein the presence of SPR indicates an SPR infection.

6. (Amended) The method of any of claims [claim] 5, 22, 23, or 24, wherein said patient is a male, and wherein step a) comprises collecting said sample from the urethra of said male patient, wherein said sample is a secretion found in [from] the urethra of said male patient.

9. (Amended) The method of claim 8, wherein [, following step a),] said testing comprises admixing said sample [is mixed] with saline [to form a diluted sample, and wherein, following said mixing, said diluted sample is examined] and examining said sample by microscopy.

10. (Amended) The method of any of claims [claim] 5, 22, 23, or 24, wherein said patient is a female, and wherein step a) comprises collecting a sample from the vagina of said female patient, wherein said sample is a cervico vaginal secretion from said female patient.

12. (Amended) The method of any of claims [claim] 5, 22, 23, or 24, wherein said patient has a skin eruption or lymph node abscess, and wherein the sample of step a) comprises [collecting] a secretion from said skin eruption or abscess.

14. (Amended) An instrument for collecting a sample from a male patient, wherein said sample comprises urethral secretions, said instrument comprising:

- a) a handle portion;[,]
- b) attached to said handle portion, a means for collecting secretions from the reproductive system of said [a] male patient, wherein said collecting means comprises a loop;[,] and

c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes [to come] into contact with said sample.

16. (Amended) An instrument for collecting a sample from a female patient, wherein said sample comprises cervico vaginal secretions, said instrument comprising:

- a) a handle portion;[,]
- b) attached to said handle portion, a means for collecting cervico vaginal secretions from said [a] female patient, wherein said collecting means comprises a loop;[,] and
- c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes [to come] into contact with said sample.

17. (Amended) A method of treating an SPR infection in a patient, said method comprising:

- a) diagnosing said SPR infection, and
- b) upon obtaining a positive diagnosis in step a), administering to said patient an SPR-inhibiting amount of an anti-SPR agent selected from the group consisting of itraconazole [itraconazole], ofloxacin, and metronidazole.

In the Abstract:

A marked-up version of the abstract is presented below.

The invention features a biologically pure culture of a newly identified [the] single-celled organism Spiky Rotating Cells (SPR), methods to diagnose an SPR infection in a human patient, an instrument for collecting and detecting an SPR infection, and methods for treating an SPR infection.